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Attorney's Docket No. 5718-16A

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Rao *et al.*		
Appl No.:	09/478,598	Group Art Unit:	1652
Filed:	January 6, 2000	Examiner:	P. Tung
For:	COMPOSITIONS AND METHODS FOR ALTERING AMINO ACID CONTENT OF PROTEINS		

April 27, 2001

Commissioner for Patents
Washington, DC 20231

RESPONSE TO RESTRICTION REQUIREMENT

This is in response to the Office Action dated March 27, 2001, in which the Examiner has required restriction between Group I, namely Claims 54-57, 117 and 118, Group II, namely Claims 58-83, 97-107, 115 and 116, Group III, namely Claims 84-96, and Group IV, namely Claims 108-114. Applicants hereby provisionally elect with traverse to prosecute the claims of Group I (Claims 54-57, 117 and 118) and expressly reserve the right to file divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the remaining claims.

The Examiner has indicated that the claims of Group I and those of Group II are directed to methods that are distinct both physically and functionally, that they require different process steps, reagents, and parameters, and that they result in different products. This restriction is respectfully traversed.

The claims of Group I are directed to a method for altering amino acid composition of a native protein of interest whose conformation is unavailable. Claim 1 sets forth the broadest embodiment of this method. The method comprises introducing amino acid changes into the native protein to create an engineered protein. A set of molecules that interact with the native

protein and which recognize the confirmation of the native protein is then used to confirm that the engineered protein has the confirmation of the native protein. In this manner, the amino acid composition of the native protein is altered. In some embodiments, the interacting molecules are antibodies to the native protein or dimerizing proteins that bind the native protein. In more distinct embodiments of this method, the claim further recites the methods to be used to select the site(s) where the amino acid change(s) should be made (Claim 117).

The claims of Group II represent distinct embodiments of Claim 1. Thus, independent claims 58, 69, 97, and 115 recite the same broad method of claim 1 but specify the amino acid alteration that results from implementation of the method. For example, in claims 58 and 115, the method of claim 1 is utilized to engineer a protein that retains the conformation of the native protein and which differs from the native protein in having an increased content of essential amino acids. In this manner, alteration of the amino acid composition of the native protein is achieved. In claim 115, antibodies represent the interacting molecules that are used to confirm that the protein engineered in accordance with the method of claim 1 retains the conformation of the native protein. In claim 69, the method of claim 1 is utilized to engineer a protein that retains the conformation of the native protein and which differs from the native protein in having an increased nutritional value. In claim 97, the method of claim 1 is directed to the engineering of a specific type of native protein, i.e., a vegetative storage protein, where a specific type of interacting molecule, i.e., monoclonal antibodies, is used to confirm that the engineered protein retains the conformation of the native vegetative storage protein.

Applicants respectfully submit that a search of the prior art to determine novelty and non-obviousness of the method recited in claim 1 would necessarily uncover references disclosing the use of this method in the manner recited in the claims of Group II. As the subject matter set forth in the claims of Group II is encompassed by the claims of Group I, Applicants respectfully submit that no undue burden of search would be incumbent upon the Examiner if the restriction requirement between these two groups of claims was withdrawn.

The Examiner has indicated that the claims of Group III and those of Group IV are directed to engineered proteins that would be expected to have distinct morphological,

functional, chemical, and physical properties, process of making, and process of using. This restriction is respectfully traversed.

The claims of Group III are directed to an engineered protein having altered amino acid composition. The broadest embodiment of these composition claims is set forth in claim 84. The engineered protein retains the conformation of the native protein. The engineered protein binds to a set of interacting molecules that specifically bind to the corresponding native protein whose structure serves as the template for designing the engineered protein. These interacting molecules recognize the conformation of the corresponding native protein. In some embodiments, the interacting molecules are antibodies (claims 85-86). In one embodiment, the engineered protein is a vegetative storage protein (claim 96).

The claims of Group IV are directed to a particular species of engineered protein encompassed by independent claim 84. Thus, claim 108 is an engineered vegetative storage protein, similar to that recited in claim 96 of Group I, with the exception that the interacting molecules that this engineered protein binds to is a set of monoclonal antibodies.

Applicants respectfully submit that a search of the prior art to determine novelty and non-obviousness of the engineered protein recited in claim 84 would necessarily uncover references disclosing a particular species of this engineered protein, i.e., the engineered protein recited in claim 108 of Group IV. As the subject matter set forth in claims of Group IV is encompassed by the claims of Group III, Applicants respectfully submit that no undue burden of search would be incumbent upon the Examiner if the restriction requirement between these two groups of claims was withdrawn.

Applicants have provisionally elected with traverse to prosecute the claims of Group I. However, for the reasons noted above, Applicants submit that it would be proper to withdraw the restriction between the claims of Group I and those of Group II at this time and to perform the initial search on these rejoined claims. Applicants therefore respectfully request reconsideration and withdrawal of the requirement between Group I and Group II claims.

Should the Examiner have further questions or comments with respect to examination of this case, it is respectfully requested that the Examiner telephone the undersigned so that further examination of this application can be expedited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those, which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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